MOUVEMENT ALLAITEMENT DU QUÉBEC

Submission to Health Canada

As part of the public consultation on:

Proposed risk-based approach for the authorization of infant food for a special dietary purpose

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LIST OF ACRONYMS

EU – European Union

FAO – Food and Agriculture Organization of the United Nations

FDA – U.S. Food and Drug Administration

FRA – Foreign Regulatory Authorities

FSANZ – Food Standards Australia New Zealand

FSDP – Foods for Special Dietary Purposes

GRAS – Generally Recognized as Safe

MAQ – Mouvement allaitement du Québec

NIH – National Institutes of Health

U.S. – United States

WHA – World Health Assembly

WHO – World Health Organization

1. INTRODUCTION AND CONTEXT

This submission is presented in response to Health Canada's consultation on the proposed risk-based approach for the authorization of foods for special dietary purpose (FSDP) intended for infants. ***Mouvement allaitement du Québec*** **(MAQ) welcomes the opportunity to contribute to this consultation, given the profound implications that regulatory choices in this area may have for infant health, public health protection, and the State's obligations towards a highly vulnerable population.**

The fact that the proposed reform is explicitly presented as responding to requests from industry raises significant concerns regarding regulatory governance. When a reform affecting products intended for a highly vulnerable population is driven primarily by considerations related to reducing administrative burdens for manufacturers and importers, there is a genuine risk that the protection of public health may be relegated to a secondary role.

By replacing, for a substantial proportion of products (approximately 70%), pre-market authorization mechanisms with post-market notification regimes that rely largely on corporate responsibility, the proposed approach closely resembles a form of self-regulation. In the context of products that may serve as a primary or sole source of nutrition for infants, such an approach is difficult to reconcile with the State's obligations to protect infant health and rights. Strengthening public, independent, and preventive regulatory oversight therefore appears not only justified, but necessary.

More broadly, the risk-based approach proposed to facilitate the introduction of new products onto the Canadian market is driven by the needs of the commercial milk products industry. Health Canada has not provided a corresponding assessment of population-level nutritional needs to justify the introduction of new or "innovative" infant feeding products from a public health perspective. Independent research grounded in infant and young child nutrition—particularly with respect to healthy term infants and infants with special medical needs who are not breastfed or who may require commercial products to supplement breastfeeding—should inform determinations of which products are necessary to support best practices in infant and young child feeding.

Prioritizing industry-driven requests to market and trade products over independently substantiated health needs, risks potential industry driven solutions. This undermines the proposed modernization and calls into question its capacity to be genuinely responsive to the needs of infants, families and consumers.

In light of these concerns, MAQ puts forward the following recommendations, which are summarized in the table below and elaborated upon in the subsequent sections of this submission.

1.1 Summary of recommendations

1	MAQ recommends that the Government of Canada implement a comprehensive Canadian Code for the Marketing of Breast-milk Substitutes across all relevant federal regulatory and policy frameworks.
2	MAQ recommends that Health Canada exclude the breastmilk substitute industry from consultations, regulatory reviews and policy development processes related to infant feeding and breastfeeding. This exclusion is necessary to prevent real or potential conflicts of interest and to safeguard Health Canada's independence, public trust, credibility and public health orientation of regulatory decision-making.
3	MAQ recommends that Health Canada explicitly integrate the protection of breastfeeding as a public health objective within any modernization of the regulatory framework applicable to foods for special dietary purpose (FSDP) intended for infants.
4	MAQ recommends that Health Canada refrain from using a risk-based approach as the primary framework for modernizing the regulatory framework applicable to foods for special dietary purpose (FSDP) intended for infants.
5	MAQ recommends that Health Canada refrain from basing Canadian authorization decisions on foreign regulatory authorities as a primary regulatory mechanism, and instead require independent, Canadian, product-specific pre-market evaluation and authorization of infant formulas and infant formula ingredients.
6	MAQ recommends that Health Canada base its regulatory decisions on the requirement for a clear pre-market demonstration of safety and that, where such a demonstration is not possible, heightened data requirements and enhanced pre-market scrutiny be applied prior to market authorization. Health Canada should also ensure transparency in regulatory decision-making by clearly documenting and publicly disclosing the scientific basis underlying authorization decisions.
7	MAQ recommends that Health Canada ensure that the best interests of the child and the right to the highest attainable standard of health are a primary consideration in all regulatory decisions affecting infant foods for special dietary purpose (FSDP), and that these obligations not be subordinated to considerations of regulatory efficiency, market access, or commercial interests.
8	MAQ recommends that Health Canada maintain and strengthen robust pre-market authorization and oversight requirements for all infant food for special dietary purpose (FSDP), including products proposed for classification under Tier 1.

2. THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES

The *International Code of Marketing of Breast-milk Substitutes* and relevant subsequent World Health Assembly resolutions (hereinafter referred to as "the Code") establish a global public health framework aimed at protecting breastfeeding and infant health through strict controls on the marketing of breastmilk substitutes. The Code recognizes that inappropriate marketing practices can undermine breastfeeding, mislead caregivers and expose infants to avoidable health risks, particularly in contexts where commercial milk products may be presented as equivalent or superior alternatives to breastfeeding. The Code urges governments to take action to give effect to the principles and aim of the Code, including legislation, regulations or other suitable measures.

The Code was adopted at the World Health Assembly in 1981 by 118 Member States, including Canada.

Any regulatory modernization affecting foods for special dietary purpose (FSDP) intended for infants should therefore ensure full alignment with the objectives and principles of the Code, including restrictions on marketing practices, the prevention of conflicts of interest and the provision of accurate, clear and appropriate information to caregivers of infants. These safeguards are essential to ensure that regulatory reforms do not inadvertently normalize the commercial promotion of breastmilk substitutes nor minimize the States' obligation to protect breastfeeding.[1]

Although the Code does not explicitly employ the terminology of "risk-based regulation," its provisions and relevant subsequent World Health Assembly resolutions clearly situate breastmilk substitutes within a preventive public health framework that requires heightened regulatory oversight and strong government responsibility. The Code does not support regulatory approaches that would treat such products as low-risk foods, rely primarily on post-market controls or shift responsibility for safety and compliance to industry-led mechanisms.

A non-exhaustive list of relevant provisions of the Code that frame the issues raised in this consultation is provided in Appendix A.

[1] Public Health Agency of Canada. (2026). *Protecting, promoting and supporting breastfeeding: Canadian recommendation and the ten steps to successful breastfeeding*. https://www.publications.gc.ca/site/eng/9.877605/publication.html

Recommendation 1

Considering the objectives and principles of the *International Code of Marketing of Breast-milk Substitutes*, adopted by the World Health Assembly and supported by Canada, as well as relevant subsequent World Health Assembly resolutions, **MAQ recommends that the Government of Canada implement a comprehensive Canadian Code for the Marketing of Breast-milk Substitutes across all relevant federal regulatory and policy frameworks.**

A Canadian Code would legislate robust restrictions on marketing practices, prevent conflicts of interest and set clear requirements regarding the provision of accurate, appropriate, and non-promotional information to caregivers of infants.

The implementation of a Canadian Code should apply across all regulatory jurisdictions affecting infant feeding products, including foods for special dietary purpose (FSDP). It should also explicitly prevent i) regulatory approaches that normalize breastmilk substitutes as low-risk products, ii) reliance primarily on post-market controls or iii) shifting responsibility for safety, compliance and public health protection to industry-led mechanisms.

Recommendation 2

MAQ recommends that Health Canada exclude the breastmilk substitute industry from consultations, regulatory reviews and policy development processes related to infant feeding and breastfeeding. This exclusion is necessary to prevent real or potential conflicts of interest and to safeguard Health Canada's independence, public trust, credibility and public health orientation of regulatory decision-making. Such an approach is consistent with best practices in public health governance and reflects the precedent established during the revision of Canada's Food Guide, in which industry actors were excluded from the review process to protect its integrity.

3. BREASTFEEDING RATES AND PUBLIC HEALTH

Canada's breastfeeding surveillance data indicate that while over 90% of mothers initiate breastfeeding, rates of exclusive breastfeeding decline sharply in the early postpartum period, dropping to approximately 72.5% within the first month and to 38.2% by six months.[2] This pattern suggests the presence of multiple systemic, social, and structural barriers that prevent many mothers from achieving their breastfeeding intentions and from meeting Health Canada and World Health Organization recommendations. Suboptimal breastfeeding is associated with a well-documented increase in health risks for both infants and mothers, with disproportionate

[2] Government of Canada. (2024, October 31). *Breastfeeding in Canada – Health Infobase*. Canada.ca. https://health-infobase.canada.ca/breastfeeding/

impacts observed in Indigenous and marginalized communities.[3] Indeed, the introduction of commercial infant formula as a substitute for breastfeeding results in avoidable adverse health outcomes and increased long-term costs for families, health systems, and society.[4]

These public health implications must be explicitly taken into account in Health Canada's consultation on the proposed risk-based approach for the authorization of foods for special dietary purpose (FSDP) intended for infants. Regulatory modernization should include safeguards that protect breastfeeding and remain fully aligned with Health Canada's infant feeding recommendations, including *Nutrition for Healthy Term Infants (0 to 6 months)*.[5]

In the absence of robust marketing restrictions consistent with the Code, the expansion of commercial infant feeding products and the facilitation of market access for products that compete with breastfeeding, risks shifting onto health care providers the responsibility for mitigating the effects of such competition on breastfeeding practices and on maternal and infant health. This dynamic increases pressure on health systems by raising the demand for clinical and community-based support required to support mothers' intentions and facilitate infant feeding practices aligned with public health recommendations.[6]

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[3] Meek JY, Noble L. Technical Report: Breastfeeding and the Use of Human Milk. Pediatrics. 2022 Jul 1;150(1):e2022057989. doi: 10.1542/peds.2022-057989. PMID: 35921641.

[4] Rollins, N. C., Bhandari, N., Hajeebhoy, N., Horton, S., Lutter, C. K., Martines, J. C., Piwoz, E. G., Richter, L. M., Victora, C. G., & Lancet Breastfeeding Series Group. (2016). *Why invest, and what it will take to improve breastfeeding practices?* The Lancet, 387(10017), 491–504. https://doi.org/10.1016/S0140-6736(15)01044-2

[5] Health Canada, Canadian Paediatric Society, Dietitians of Canada, & Breastfeeding Committee for Canada. (2012/2013). *Nutrition for Healthy Term Infants: Recommendations from birth to six months* [Joint statement]. Government of Canada. https://www.canada.ca/en/health-canada/services/canada-food-guide/resources/nutrition-healthy-term-infants/nutrition-healthy-term-infants-recommendations-birth-six-months.html

[6] Pérez-Escamilla, R., Tomori, C., Hernández-Cordero, S., Baker, P., Barros, A. J. D., Bégin, F., Chapman, D. J., Grummer-Strawn, L. M., McCoy, D., Menon, P., Ribeiro Neves, P. A., Piwoz, E., Rollins, N., Victora, C. G., Richter, L., & The Lancet Breastfeeding Series Group. (2023). Breastfeeding: Crucially important, but increasingly challenged in a market-driven world. The Lancet, 401(10375), 472–485. https://doi.org/10.1016/S0140-6736(22)01932-8

Recommendation 3

Considering the well-documented health risks associated with suboptimal breastfeeding for both infants and mothers, the disproportionate impacts observed in Indigenous and marginalized communities and according to Canada's breastfeeding dashboard, **MAQ recommends that Health Canada explicitly integrate the protection of breastfeeding as a public health objective within any modernization of the regulatory framework applicable to foods for special dietary purpose (FSDP) intended for infants.**

Regulatory decision-making should take into account the downstream impacts on health systems, including the increased demand placed on clinical and community-based services to mitigate the effects of market-driven competition with breastfeeding and ensure full alignment with Health Canada's infant feeding recommendations, including Nutrition for Healthy Term Infants (0 to 6 months).

4. SCIENTIFIC LIMITATIONS OF THE RISK-BASED APPROACH

The scientific literature highlights that traditional food safety assessment methods, including risk-based approaches, present significant limitations when applied to the evaluation of certain bioactive ingredients added to commercial infant formulas.[7] These methods, which were originally designed to detect acute or classical toxic effects, are poorly suited for assessing ingredients that may exert complex or long-term biological effects on child development. This methodological limitation complicates the rigorous assessment of the safety of new or modified formulations and calls into question the ability to robustly classify such products as "low risk."

4.1 Complexity of assessing immune effects in infants

The evaluation of nutritional effects on the infant's immune system is widely recognized as particularly complex. Early immune development coincides with multiple major physiological adaptations, including the establishment of the gut microbiota, adaptation to extrauterine life and exposure to a range of perinatal environmental factors. This complexity makes it difficult to clearly attribute immune effects to a specific ingredient or formulation change, thereby increasing the scientific uncertainty surrounding the long-term safety of new infant formula compositions.[8]

Experts also highlight the absence of reliable and standardized safety biomarkers that would allow for robust evaluation of the long-term effects of bioactive ingredients in infants. Variability in research methodologies, study populations and measured outcomes, limits the ability to use

[7] Greer FR et al. *Safety assessment of bioactive ingredients in infant nutrition*. American Journal of Clinical Nutrition, 2022.
[8] Ibid.

many biological indicators as relevant safety endpoints. This situation reduces the reliability of pre-market assessments and further reinforces uncertainty regarding potential long-term effects, particularly in the case of novel ingredients or incremental modifications to existing formulations.

4.2 Biotechnology and bioengineering

Several ingredients recently introduced into commercial infant formulas are derived from biotechnological processes, notably through microbial fermentation using genetically modified microorganisms. Although these ingredients are purified and compliant with current safety standards, their large-scale use in infant nutrition remains relatively recent.

Given the particular vulnerability of infants, their exclusive exposure to these products, and the persistent scientific uncertainty regarding the long-term effects of certain biosynthetic or bioactive ingredients, it is essential that such products be subject to rigorous pre-market regulatory evaluation. In this context, a risk-based approach should lead to the strengthening, rather than the relaxation, of pre-market authorization mechanisms for ingredients derived from food biotechnology.

This scientific uncertainty led the United States (US) Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to convene working sessions and workshops to discuss, among other issues, appropriate assessment frameworks for bioactive ingredients in commercial infant formulas. The joint FDA–NIH workshops, entitled *Exploring the Science Surrounding the Safe Use of Bioactive Ingredients in Infant Formula: Considerations for an Assessment Framework,* were held in September 2021. Discussions from these joint workshops resulted in the publication of a U.S. federal document entitled *Science Surrounding the Safe Use of Bioactive Ingredients in Infant Formula: Federal Comment,* published in February 2023.[9]

This commentary document on bioactive ingredients used in commercial infant formulas highlights that the science surrounding their safety remains emerging and that substantial uncertainties persist.

> « Throughout the presentations and discussions, a reoccurring theme of “we don’t know yet” was echoed by the speakers on many topics, indicating the emerging nature of human milk and infant formula bioactive ingredient research. Other themes included:
>
> - an appreciation for the ever-increasing complexity in human milk research that is the primary basis of most research in infant formula innovations

[9] National Institutes of Health & U.S. Food and Drug Administration. (2023). *Science surrounding the safe use of bioactive ingredients in infant formula: Federal comment*. *Pediatric Research, 94*, 420–422. https://www.nature.com/articles/s41390-023-02512-6.pdf

- the variability in human milk composition and volume among mother-infant dyads and during different phases of lactation, making it difficult to determine optimum bioactive ingredient concentrations for addition to infant formula and to predict quantitative response(s) to any given bioactive milk constituent used as an infant formula ingredient
- a need for in-depth, long-term studies to determine the function and safety of bioactives for use in infant formula, but a lack of consensus on the required length of clinical study follow-up periods
- that while much is unknown about the effects of single bioactive milk constituents, even less is known about the potential for interactions between these bioactive constituents under different conditions and within an infant formula matrix, suggesting that model systems for evaluating these effects need to be expanded
- a need for the development of a more standardized approach for evaluating the function and safety of bioactive infant formula ingredients, including model systems, databases of information on infants and children, and big data analytics»[10]

This excerpt from the commentary document on bioactive ingredients used in commercial infant formulas highlights that the science surrounding their safety remains emerging and that significant uncertainties persist. As noted by participants in one of these joint workshops, "we don't know yet" with respect to many aspects of these ingredients, due to variability in human milk composition, the lack of consensus regarding the appropriate duration of clinical follow-up and limited knowledge about interactions among bioactive constituents within an infant formula matrix. These observations underscore the need for comprehensive, long-term studies to determine the function and safety of these ingredients before their use is generalized.

Recommendation 4

Considering the particular vulnerability of infants, their sometimes exclusive exposure to foods for special dietary purpose (FSDP), the limitations of risk-based assessment methods, and the persistent scientific uncertainty surrounding bioactive ingredients, including those classified as optional ingredients, **MAQ recommends that Health Canada refrain from using a risk-based approach as the primary framework for modernizing the regulatory framework applicable to foods for special dietary purpose (FSDP) intended for infants.** Instead, Health Canada should prioritize a preventive regulatory approach based on a rigorous pre-market authorization regime for these products, in order to ensure adequate protection of infant health.

5. RELIANCE ON FOREIGN REGULATORY AUTHORITIES (FRA)

The proposed risk-based approach suggests relying, in part, on authorization processes from foreign regulatory authorities (FRA). While international alignment can be valuable, this approach raises concerns when the regulatory frameworks being referenced are fundamentally

[10] National Institutes of Health & U.S. Food and Drug Administration, *Science surrounding the safe use of bioactive ingredients in infant formula: Federal comment*, *Pediatric Research, 94* (2023), p. 421.

different in nature, scope and intent. In particular, consistent violations of regulatory requirements in some jurisdictions heighten the risk of importing products that may be unsafe, nutritionally inadequate or non-compliant with Canadian public health standards.

5.1 US Food and Drug Administration

Health Canada states that under the U.S. Food and Drug Administration (FDA) framework, a *pre-market notification approach* applies to all infant formulas, including medical infant formulas, and that these products must meet regulatory requirements, including compositional standards. This description implies a level of regulatory approval or pre-market authorization. However, the FDA explicitly states that it does not approve infant formulas.[11] Instead, manufacturers are responsible for notifying the agency before marketing a new formula, after which FDA staff reviews submissions to assess whether products appear to meet existing regulatory requirements related to nutrition, labeling and safety. This system is primarily manufacturer-driven and compliance-based, rather than an authorization or approval framework.[12]

Furthermore, this compliance-based framework exists in a context where the United States has not established federal limits for key toxic heavy metals in infant formula. Independent testing organizations have confirmed that, in the absence of federal standards, assessments of heavy metal exposure from infant formula rely on non-binding international or health-based reference values rather than enforceable FDA regulatory limits.[13,14].

While the FDA uses a "Closer to Zero" initiative to establish action levels for lead and other toxic elements in certain foods intended for babies and young children, these action levels explicitly do not apply to infant formula. The FDA has stated that infant formula is excluded from the

[11] U.S. Food and Drug Administration. (2025). *Infant formula*. U.S. Department of Health and Human Services. https://www.fda.gov/food/resources-you-food/infant-formula
[12] *Ibid*.
[13] Collado-López, S., Rodríguez Hernández, M. F., Mariscal-Moreno, R. M., Téllez-Rojo, M. M., Betanzos-Robledo, L., Reyes Luna, M., & Cantoral-Preciado, A. (2026). Concentrations of heavy metals in processed baby foods and infant formulas worldwide: A scoping review. Nutrition Reviews, 84(2), 448–461. https://pubmed.ncbi.nlm.nih.gov/40972552/
[14] Kirchner, L. (2025, March 18). *We tested 41 baby formulas for lead and arsenic*. Consumer Reports. https://www.consumerreports.org/babies-kids/baby-formula/baby-formula-contaminants-test-results-a7140095293/

scope of this guidance.[15] This distinction underscores a U.S. regulatory approach that emphasizes market and supply considerations over a precautionary, authorization-based framework.

A central goal of the FDA action plan is to increase market resiliency and supply continuity, including encouraging new market entrants and increasing production flexibility. While these objectives are important, they are not equivalent to a precautionary, authorization-based approach focused on infant health protection, particularly for infants with special dietary or medical needs.[16]

Basing Canadian authorization decisions on a system prioritizing market recovery and supply expansion may inadvertently shift the focus away from rigorous, product-specific pre-market assessment.

Furthermore, under current U.S. legislation, new ingredients that are considered "Generally Recognized As Safe" (GRAS) for use in infant formula are not required to undergo pre-market approval by the U.S. Food and Drug Administration (FDA). Instead, manufacturers may rely on self-affirmed GRAS determinations, provided that the ingredient meets the GRAS provisions of the *Federal Food, Drug, and Cosmetic Act*.[17]

While infant formula manufacturers are strongly encouraged to notify the FDA of their GRAS self-determinations prior to submitting a new infant formula notification, such notification has historically been voluntary rather than mandatory. This approach places a significant portion of the safety assessment responsibility on industry.

The FDA's recent announcement of plans to publish a proposed rule that would require mandatory submission of GRAS notices, eliminate self-affirmed GRAS determinations and expand public transparency represents a positive and necessary step toward strengthening oversight. This acknowledgement by the FDA itself underscores the limitations of the existing framework.

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[15] U.S. Food and Drug Administration. (2025, January 6). FDA issues final guidance for industry on action levels for lead in processed food intended for babies and young children. U.S. Department of Health and Human Services. https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-setting-action-levels-lead-processed-food-intended-babies-and-young-children

[16] U.S. Food and Drug Administration. (2025). *Long-term national strategy to increase resiliency of the U.S. infant formula market*. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/long-term-national-strategy-increase-resiliency-us-infant-formula-market

[17] U.S. Food and Drug Administration. (n.d.). *Generally recognized as safe (GRAS)*. https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

While this proposed rule is commendable, it also reinforces the importance of Health Canada maintaining regulatory independence, including the need for Canada to conduct its own independent assessment and approval of infant formula and infant formula ingredients.

5.2 European Union - European Commission

Reliance on the European Union's (EU) infant formula regulatory framework poses a risk for Health Canada since EU oversight is not centralized and does not involve a uniform authorization or pre-market approval process. Under Article 12 of *Commission Delegated Regulation (EU) 2016/127*, manufacturers are only required to notify the competent authority of each individual Member State where an infant formula is marketed by submitting the product label and any additional information requested. This notification mechanism does not constitute an EU-level authorization, approval or harmonized scientific review.[18]

As a result, the scope, depth and rigor of regulatory scrutiny vary significantly across Member States, depending on national enforcement capacity, resources and regulatory priorities. There is no centralized EU authority that evaluates infant formula composition, novel ingredients or cumulative risk before products enter the market. Consequently, the fact that a formula is legally marketed in one or more EU Member States provides no consistent, transparent or verifiable assurance of the level of safety assessment conducted.

For Health Canada, reliance on the EU market presence as a proxy for safety or regulatory adequacy, therefore creates regulatory uncertainty and undermines Canada's ability to independently assess risks. This is particularly concerning given the high vulnerability of the infant population, for whom even small variations in formulation or ingredient safety can have significant health implications. In the absence of centralized EU authorization or standardized review, deference to the EU framework limits Health Canada's capacity to ensure that infant formula products meet Canada's own evidence-based safety standards.

5.3 Food Standards Australia New Zealand

Health Canada's reliance on Food Standards Australia New Zealand (FSANZ) regulations as a proxy for product safety or regulatory adequacy is inherently constrained, given that FSANZ does not conduct product-by-product authorization. FSANZ's mandate is to develop and amend the *Australia New Zealand Food Standards Code*, not to approve or authorize individual food

[18] European Commission. (2016). *Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formula, Article 12 (Notification)*. *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0127

products prior to market entry. Once a standard is in force, any product that meets its requirements may be marketed without notification to, or review by, FSANZ.[19]

While FSANZ does require a mandatory proposal and risk assessment process for innovations that fall outside existing standards, such as the introduction of a new substance, the creation of a new food category or significant changes to compositional requirements, this process applies only when a regulatory amendment is sought.[20] Products that conform to existing standards may therefore enter the market without any contemporary assessment of their formulation, cumulative exposure or suitability for highly vulnerable populations, such as infants.[21]

As a result, Australian market presence alone provides Health Canada with no reliable insight into the regulatory pathway a product followed. There is limited visibility into whether a product's ingredients and composition were subject to a robust, transparent safety assessment or whether they merely complied with a pre-existing standard that may reflect different policy objectives, exposure assumptions or risk tolerances than those applied in Canada.

For Health Canada, reliance on FSANZ compliance as a proxy for safety therefore undermines independent risk evaluation and constrains Canada's ability to ensure that products meet its own evidence-based standards for infant health protection.[22]

[19] Food Standards Australia New Zealand. (n.d.). *Food Standards Code legislation*. https://www.foodstandards.gov.au/food-standards-code/legislation
[20] Food Standards Australia New Zealand. (2024, June). *Approval report – Proposal P1028: Infant formula*. https://www.foodstandards.gov.au/sites/default/files/2024-06/Approval%20Report%20-%20Proposal%20P1028%20Infant%20Formula.pdf
[21] Food Standards Australia New Zealand Act 1991 (Cth). (2024). *Federal Register of Legislation*. https://www.legislation.gov.au/C2004A04193/2024-10-14/2024-10-14/text/original/epub/OEBPS/document_1/document_1.html
[22] Food Regulation. (n.d.). *About the system: Implementation & enforcement*. https://www.foodregulation.gov.au/about-the-system/implementation-enforcement

Recommendation 5
Considering the particular vulnerability of infants, their sometimes exclusive reliance on infant formula as a primary or sole source of nutrition and the structural limitations of several foreign regulatory frameworks—including reliance on manufacturer-driven notification systems, self-determined safety assessments and decentralized or non-product-specific oversight—**MAQ recommends that Health Canada refrain from basing Canadian authorization decisions on foreign regulatory authorities as a primary regulatory mechanism and instead require independent, Canadian, product-specific pre-market evaluation and authorization of infant formulas and infant formula ingredients**, consistent with a precautionary approach and with the State's obligations to ensure a high level of protection for infant health.

6. A REGULATORY APPROACH BASED ON THE PRECAUTIONARY PRINCIPLE

6.1 The vulnerability of infants in relation to nutrition

Infant formulas are intended for a highly vulnerable population. While some infants are exclusively breastfed, others are partially fed with infant formula or rely on it as their primary or sole source of nutrition. In these circumstances, the composition of infant formulas has a direct influence on the safety and nutritional adequacy of an infant's diet.[23,24,25]

In this context, classifying products as "low risk" must be approached with extreme caution, given the potentially serious and irreversible consequences of inadequate exposure.[26] Variations in formula composition can lead to severe and irreversible effects on infant health, thereby necessitating rigorous evaluation prior to any designation as low risk. Similarly, a regulatory approach that reduces pre-market authorization requirements in favour of predominantly post-market mechanisms raises significant concerns regarding health protection. Any assessment of such an approach must be firmly grounded in the precautionary

[23] Santé Canada. (s.d.). *Préparations pour nourrissons*. Gouvernement du Canada. https://www.canada.ca/fr/sante-canada/services/soins-nourrissons/preparations-pour-nourrissons.html
[24] U.S. Food and Drug Administration. (n.d.). *Infant formula*. https://www.fda.gov/food/resources-you-food/infant-formula
[25] Abrams, S. A., & Daniels, S. R. (2019). Protecting vulnerable infants by ensuring safe infant formula use. *The Journal of Pediatrics, 211*, 15–17. https://doi.org/10.1016/S0022-3476(19)31093-5
[26] Bakshi, S. et al. (2023). A comprehensive review on infant formula: Nutritional and functional constituents, recent trends in processing and its impact on infants' gut microbiota. Frontiers in Nutrition, 10, 1194679.

principle and in the State's obligations to protect vulnerable populations, rather than in considerations related to administrative simplification or process efficiency.

6.2 The Codex Alimentarius explicitly integrates the precautionary principle into food safety risk analysis

The Codex Alimentarius Commission established the *Code of Ethics for International Trade in Foods (CXC 20-1979)*. This Code of Ethics articulates principles for the ethical conduct of international food trade with the explicit objectives of protecting consumer health and ensuring fair practices in the food trade. Within this framework, national authorities are expected to exercise regulatory oversight that places the protection of public health at its core, particularly in relation to foods that may present heightened risks to vulnerable populations.

In fulfilling these responsibilities, national authorities are required to ensure compliance with their obligations under the *International Health Regulations* (2005) with respect to food safety events, including timely notification, reporting and verification to the World Health Organization. They are also expected to ensure that the *Code of Marketing of Breast-milk Substitutes* and relevant subsequent World Health Assembly resolutions, which establish principles for the protection of breastfeeding, are respected and effectively implemented as part of a coherent public health approach to infant feeding. The normative frameworks of the Codex Alimentarius governing food safety risk analysis explicitly recognize that scientific uncertainty is an inherent component of risk assessment and must be taken into account in regulatory decision-making.[27,28]

The principles adopted by the Codex Alimentarius Commission and set out in the document *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, establish that risk analysis must be conducted in a structured and transparent manner and that it must be re-evaluated in light of new scientific evidence as it becomes available. This requirement implies that the limitations, variability and evolving nature of scientific knowledge be explicitly considered throughout the entire risk analysis process.

[27] Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, Codex Procedural Manual, Appendix IV, FAO/OMS, 2003.
https://www.fao.org/4/a0247e/a0247e04.htm
[28] Codex Alimentarius Commission, *Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007), FAO/OMS, 2007.
https://www.fao.org/input/download/standards/10751/CXG_062e.pdf

The Codex guideline intended for application by governments (*Principles for Risk Analysis for Food Safety for Application by Governments*, CAC/GL 62-2007) states even more explicitly that precaution is an inherent element of risk analysis:

> "Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food-related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard."[29]

This guideline recognizes that multiple sources of uncertainty exist at both the risk assessment and risk management stages and requires that the extent of uncertainty and variability in the available scientific information must be explicitly considered in decision-making. The central objective of risk analysis, as defined by the Codex, remains the protection of human health. From this perspective, a risk-based regulatory approach is not limited to the identification of established hazards or the quantification of known risks. It also encompasses the prudent evaluation of situations in which scientific knowledge is incomplete, uncertain or evolving.

The Codex framework therefore does not support an interpretation of the risk-based approach that would, in the presence of significant uncertainty, lead to a systematic shift of control mechanisms to the post-market phase. On the contrary, it provides that risk management measures should be proportionate not only to the level of identified risk, but also to the degree of scientific uncertainty.

In this context, shifting the majority of infant formula products to a post-market notification regime effectively transfers primary responsibility for regulatory compliance from Health Canada to manufacturers, resulting in a model that relies heavily on industry self-regulation. Such an approach necessarily increases reliance on post-market surveillance by Health Canada and the Canadian Food Inspection Agency. Without a robust, adequately resourced, and effective post-market surveillance system that fully meets Codex hygienic and compositional requirements, this shift in regulatory responsibility carries a risk of delayed detection of safety issues, with potentially serious consequences for infant health.

When applied to infant nutrition, these principles lead to an enhanced requirement for caution. Commercial infant formulas are intended for a particularly vulnerable population and may constitute a primary or exclusive source of nutrition. In this context, the explicit integration of scientific uncertainty into risk analysis, as prescribed by the Codex, supports the maintenance of robust pre-market authorization mechanisms and high evidentiary requirements prior to

[29] Codex Alimentarius Commission, *Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007), section 2.1. https://www.fao.org/input/download/standards/10751/CXG_062e.pdf

market entry.[30] A risk-based approach that is consistent with Codex principles thus leads to strengthened upstream controls when data are uncertain, rather than their relaxation.

6.3 History of safe use: risks and impacts on infant health

Health Canada does not provide a definition of "history of safe use" as an indicator for assessing risks in Tier 1 and Tier 2, nor does it specify the metrics used to determine safety. Instead, the term is used as a subjective indicator, allowing broad flexibility in its interpretation. **Past safety does not preclude emerging risks and does not take into account batch-to-batch variability, compositional changes, modifications to manufacturing processes, or technological changes in ingredient production.**

"History of safe use" also fails to consider well-established short-term health consequences of formula feeding, including the differing health outcomes between breastfed and formula-fed infants, as well as manufacturing failures resulting in industrial or microbiological contamination. Nor does it take into account the long-term, lifelong health impacts associated with formula feeding.

Health Canada's proposal to consider "history of safe use" alongside its risk-based approach in order to "expedite timelines," enable "faster market entry for new infant formulas," and "enhance the availability and diversity of products in Canada" raises significant concerns. Any such products must fully comply with *the Codex Alimentarius Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)*. This requires rigorous scientific validation demonstrating their ability to support infant health as the sole source of nutrition. In addition, these products must meet all applicable safety and hygienic standards set out in *Codex Standards and Guidelines*, supported by robust regulatory mechanisms and oversight systems to ensure full compliance.

Recommendation 6

Given the insufficiency of available evidence to robustly demonstrate the long-term safety of certain ingredients and formulations intended for infant nutrition, **MAQ recommends that Health Canada base its regulatory decisions on the requirement for a clear pre-market demonstration of safety and that, where such demonstration is not possible, heightened data requirements and enhanced pre-market scrutiny be applied prior to market authorization.** Health Canada should also ensure transparency in regulatory decision-making by clearly documenting and publicly disclosing the scientific basis underlying authorization decisions, particularly where limited or incomplete data are considered sufficient to permit market entry, in keeping with the precautionary principle and the objective of protecting infant health.

[30] Codex Alimentarius Commission, *Procedural Manual*, édition récente, section « Risk Analysis ». https://openknowledge.fao.org/server/api/core/bitstreams/e96c7dbb-c396-43b3-a4c4-a1c2f84d7927/content

6.4 Compliance with the Convention on the Rights of *the Child*

First and foremost it is Health Canada's mandate to ensure that the regulations are effective and responsive to the needs of consumers, especially the most vulnerable of consumers: all infants, including premature infants, new-born infants and infants with special medical needs.

Canada ratified the *Convention on the Rights of the Child* in 1991 and is therefore obligated to put into effect meaningful measures that "recognize the right of the child to the enjoyment of the highest attainable standard of health".[31] In accordance with Article 3 of the *Convention on the Rights of the Child*, the best interests of the child must be a primary consideration in all regulatory decisions affecting infant health, and cannot be subordinated to commercial or market-based considerations.

The proposed risk-based approach prioritizes measures intended to facilitate the self-regulation of commercial milk-based products, including reducing barriers, decreasing regulatory "red tape," supporting access to products, reducing what are characterized as unnecessary regulatory burdens, facilitating importation, supporting innovation, increasing efficiency, enabling timely access, reducing administrative burden, expediting market entry timelines, etc.

This reduction in regulatory oversight, which gives precedence to the commercial and marketing interests of the infant formula industry, risks undermining Canada's obligations under the *Convention on the Rights of the Child* to integrate child rights into law, policy, and practice, particularly where regulatory decisions may directly affect infant health outcomes.

Regulatory flexibility must be demonstrably compatible with Canada's obligations under the *Convention on the Rights of the Child*, particularly where decisions affect products that may serve as the sole source of nutrition for infants.

Recommendation 7
Considering Canada's obligations under Articles 3 and 24 of the *Convention on the Rights of the Child*, **MAQ recommends that Health Canada ensure that the best interests of the child and the right to the highest attainable standard of health are a primary consideration in all regulatory decisions affecting infant foods for special dietary purpose (FSDP) and that these obligations not be subordinated to considerations of regulatory efficiency, market access or commercial interests.**

[31] United Nations. (1989). *Convention on the Rights of the Child*. United Nations Treaty Series, 1577, 3. https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child

7. RECURRING CONTAMINATION OF INFANT FORMULA AND IMPLICATIONS FOR REGULATORY OVERSIGHT

Frequent recalls of a wide range of commercial milk-based products contaminated with *Cronobacter sakazakii*, *Salmonella* species, *Bacillus cereus*, *Clostridium botulinum* and other microorganisms have resulted in unsafe products entering the marketplace and, in some cases, serious illness among infants consuming these products. These recurring contamination events demonstrate the ongoing vulnerability of infant formula and underscore the need for strengthened regulatory oversight.[32]

To better understand the persistence of these risks, it is important to consider the microbiological dynamics occurring throughout the production and handling of infant formula.[33] Despite the application of heat treatments during manufacturing, certain thermoduric and spore-forming microorganisms survive processing and remain present in the final product.[34] As reported by Fusi et al (2025) :

> « Changes in microbial population occur during the production of powdered formula; in a study by Xiong et al., most of the present bacteria were eliminated by pasteurization process with the exception of some Enterococcus spp. and Streptococcus thermophilus. During mixing, evaporation, and spray-drying, the main surviving species were Enterococcus faecium, Lactococcus lactis, Lactobacillus plantarum, and spore formers, like Bacillus stearothermophilus and Bacillus licheniformis. The presence of microorganisms in the final product can be therefore attributed to thermoduric and spore-forming bacteria that survive pasteurization; other sources to be considered are the addition of lactic acid bacteria, the contamination from ingredients that are heat-treated separately, and the contamination of the processing environment during drying. Once the powdered formula is produced, no further decontamination can be applied. Microbial growth of surviving microorganisms in the product is virtually impossible, owing to the extremely low water activity (0.17–0.22 according to Gurtler & Beuchat); nonetheless, the survival of C. sakazakii, Salmonella spp., L. monocytogenes and E.

[32] Fusi, V., Stella, S., Bernardi, C., & Tirloni, E. (2025). *Microbiological characteristics of powdered infant and follow-on formulae and safety concerns: A review*. Heliyon, 11(10), e42927. https://doi.org/10.1016/j.heliyon.2025.e42927

[33] Silano, M., Paganin, P., & Davanzo, R. (2016). Time for the 70 °C water precautionary option in the home dilution of powdered infant formula. Italian Journal of Pediatrics, 42, 17. https://doi.org/10.1186/s13052-016-0228-9 ; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4761158/

[34] World Health Organization & Food and Agriculture Organization of the United Nations. (2007). Safe preparation, storage and handling of powdered infant formula: Guidelines. World Health Organization. https://iris.who.int/server/api/core/bitstreams/423f27ea-b94d-447c-aa0c-46cdbc80e5b3/content

> coli O157:H7 has been reported for up to 1 year at 5 ◦C. An eventual contamination is of concern, as efficient growth could occur once the product is reconstituted for use. »[35]

The number of infants who become ill as a result of consuming contaminated infant formula remains unknown, as mandatory reporting of diagnosed cases is not currently in place.[36,37] While the *Code of Hygienic Practice on Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)* was developed in response to outbreaks of *Enterobacter sakazakii* (now reclassified as *Cronobacter sakazakii*) and *Salmonella* species[38], subsequent contamination events involving other pathogens have continued to necessitate product recalls and public warnings. These include spore-forming microorganisms such as *Bacillus cereus*, a toxin-producing bacterium, and the more serious *Clostridium botulinum*.[39]

In recognition of these ongoing risks, Codex, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) are currently undertaking work to revise the *Code of Hygienic Practice on Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008).[40] Heat-resistant spores of *Clostridium botulinum* and *Bacillus cereus* are ubiquitous in the environment and require high temperatures, prolonged exposure times and pressure to eliminate[41], conditions that cannot be applied to powdered infant formula without adversely affecting the nutritional integrity of products that are required to meet the nutritional specifications of applicable Codex standards. Nor is it feasible for parents and caregivers to implement measures capable of eliminating such spores during preparation or handling.

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[35] Fusi et al., 2025
[36] Public Health Agency of Canada. (2024, August 21). Cronobacter: For health professionals. Government of Canada. https://www.canada.ca/en/public-health/services/food-poisoning/cronobacter/health-professionals.html
[37] Norberg, S., Stanton, C., Ross, R. P., Hill, C., Fitzgerald, G. F., & Cotter, P. D. (2012). Cronobacter spp. in powdered infant formula. Journal of Food Protection, 75(3), 607–620. https://doi.org/10.4315/0362-028X.JFP-11-285
[38] Codex Alimentarius Commission. (2008). *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)*. Food and Agriculture Organization of the United Nations & World Health Organization. https://www.fao.org/input/download/standards/11026/CXP_066e.pdf
[39] Fusi et al., 2025.
[40] International Baby Food Action Network. (2025, December 22). Codex agrees to work on Botulinum contamination. IBFAN. https://www.ibfan.org/codex-agrees-to-work-on-botulinum-contamination/
[41] Greer FR et al., 2022.

Available evidence indicates that the majority of infant formula contamination outbreaks occur in products that would fall within the proposed Tier 1 category. Product recalls and warnings to parents and caregivers often occur only after a significant number of infants have become ill and the illnesses have been epidemiologically linked to contaminated products.[42,43,44,45,46] The proposed deregulation of Tier 1 products would therefore necessitate substantially increased reliance on post-market surveillance across all stages of ingredient sourcing, manufacturing and distribution.

Given these realities, all commercial milk-based infant formulas require strict adherence to hygienic measures and robust pre-market oversight to ensure full compliance with Codex hygienic and compositional requirements. Reliance on a "history of safe use" should not be considered a sufficient safeguard, nor a guarantor of product safety, particularly for products intended for a highly vulnerable population and that may serve as a primary or sole source of nutrition.

[42] Strysko, J., Cope, J. R., Martin, H., Tarr, C., Hise, K., Collier, S., & Bowen, A. (2020). Food safety and invasive Cronobacter infections during early infancy, 1961–2018. Emerging Infectious Diseases, 26(5), 857–865. https://doi.org/10.3201/eid2605.190858

[43] Farmer, J. J., III. (2015). My 40-year history with Cronobacter/Enterobacter sakazakii: Lessons learned, myths debunked, and recommendations. Frontiers in Pediatrics, 3, Article 84. https://doi.org/10.3389/fped.2015.00084

[44] U.S. Food and Drug Administration. (2025, November 11). ByHeart updates information regarding voluntary recall of all batches of ByHeart whole nutrition infant formula cans and packs because of possible health risk. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-updates-information-regarding-voluntary-recall-all-batches-byheart-whole-nutrition-infant

[45] Government of Canada. (2025, November 14). ByHeart whole nutrition infant formula may be unsafe due to potential presence of dangerous bacteria Clostridium botulinum. https://recalls-rappels.canada.ca/en/alert-recall/byheart-whole-nutrition-infant-formula-may-be-unsafe-due-potential-presence-dangerous

[46] Food Standards Agency. (2026, January 6). Nestlé recalls several SMA infant formula and follow-on formula as a precaution because of the possible presence of cereulide (toxin). https://www.food.gov.uk/news-alerts/alert/fsa-prin-02-2026

Recommendation 8
Considering the recurring contamination of powdered infant formula with pathogenic microorganisms, the documented limitations of post-market detection and the particular vulnerability of infants consuming these products as a primary or sole source of nutrition, **MAQ recommends that Health Canada maintain and strengthen robust pre-market authorization and oversight requirements for all infant FSDP, including products proposed for classification under Tier 1**. Health Canada should ensure that regulatory approaches governing powdered infant formula are fully consistent with Codex hygienic and compositional requirements and reflect the inherent microbiological risks associated with these products, including risks that cannot be effectively mitigated through post-market controls or by parents and caregivers during preparation.

8. CONCLUSION

In conclusion, this submission underscores the need for a comprehensive and systemic approach to infant feeding policies in Canada. This approach must recognize breastfeeding not as an individual responsibility, but as a public health priority shaped by social, commercial and policy environments. Optimal breastfeeding practices depend on enabling environments that support parents across health systems, workplaces, communities and regulatory frameworks overseeing the marketing and promotion of breastmilk substitutes.

While breastfeeding offers well-established benefits for maternal and infant health, health equity and health system sustainability, these benefits are increasingly undermined by aggressive commercial practices of the breast-milk substitutes industry, regulatory gaps in Canadian legislation and insufficient protections for infant and young child feeding.

In the absence of robust safeguards aligned with the Code of Marketing of Breast-milk Substitutes, industry influences on infant and young child feeding remain insufficiently regulated. Health Canada has a critical role to play in fostering breastfeeding-enabling environments that i) protect informed decision-making about breastfeeding, ii) prioritize the precautionary principle in approaches to infant and young child feeding and iii) ensure that commercial interests do not compromise public health objectives.

Advancing these priorities requires not only strong regulatory action but also sustained dialogue between public authorities and civil society organizations with expertise in breastfeeding and infant feeding. *Mouvement allaitement du Québec* is part of an extensive network across Canada working on these issues and remains available to meet with Health Canada to contribute to parliamentary or consultative processes and to engage in any other form of dialogue that may support the development and implementation of effective, evidence-informed policies that are aligned with the Code.

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APPENDIX A

Relevant provisions of the *International Code of Marketing of Breast-milk Substitutes* and subsequent World Health Assembly resolutions for this consultation

Article / Resolution	Scope and relevance
Article 2 — Scope of Application	Establishes that the Code applies to all breastmilk substitutes, including infant formulas, without distinction based on levels of risk. Treats these products as a distinct category requiring comprehensive regulatory oversight rather than differentiated risk classification.
Article 4.2 — Responsibility of Public Authorities	Assigns primary responsibility to governments to ensure that information on infant feeding is objective, consistent, and aligned with public health objectives, affirming the central regulatory role of the State rather than reliance on manufacturers or post-market controls.
Article 10 — Product Quality	Requires breastmilk substitutes to be of high quality and compliant with generally accepted standards, implicitly referencing Codex Alimentarius standards as a minimum benchmark for safety and quality, not as a justification for reduced oversight.
WHA39.28 (1986) — Marketing of Breastmilk Substitutes	Reinforces government responsibility for implementing and enforcing the Code and underscores the need for strict regulation of commercial practices to protect infant health.
WHA58.32 (2005) — Infant and Young Child Nutrition	Calls on Member States to prevent the use of nutrition and health claims for breastmilk substitutes, reflecting a preventive approach to potential health risks even in the absence of demonstrated harm.
WHA65.6: (2012) - safeguarding against conflict of interest	Urges Member States to put into practice comprehensive plan on maternal, infant and young child nutrition, including: 1. developing or strengthening legislative, regulatory or other measures to control the marketing breastmilk substitutes: 2. Establishing adequate mechanisms to safeguard against potential conflict of interest in nutrition action.
WHA69.9 (2016) — Ending Inappropriate Promotion of Foods for Infants and Young Children	Reaffirms that breastmilk substitutes and related products require heightened regulatory oversight to prevent practices that undermine breastfeeding and public health objectives.
WHA71.9 (2018) — Infant and Young Child Feeding	Strengthens Member States' commitments to protect breastfeeding and regulate breastmilk substitutes within a comprehensive public health and preventive regulatory framework.